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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,986	01/17/2002	Richard John Warby	12654-38018	5632

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EXAMINER

EREZO, DARWIN P

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,986

Applicant(s)

WARBY, RICHARD JOHN

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-40 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-40 and 42-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 43-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 43-46, which is dependent on claim 32, recites an apparatus comprising a housing for a container, a mouthpiece, and a duct connecting an outlet of the container to the mouthpiece. However, claim 32 recites the apparatus as a Markush grouping consisting of an inhaler, an inhaler housing,... and a foil storage type. The applicant has not disclosed in the specification of a foil storage type comprising a mouthpiece and a duct.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 32, 33 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,576,068 to Caburet et al. in view of US 5,758,774 to Leblong.

Caburet teaches a method comprising the step of using cold plasma polymerization (col. 3, lines 8-11) to create a layer of one or more cold plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of an apparatus for dispensing a medicament (col. 1, lines 6-12), which surfaces come into contact with medicament during storage or dispensing, wherein the cold plasma polymerized monomer is siloxane monomers (col. 3, line 14). Caburet is silent with regards to the storage apparatus being a foil storage type.

Leblong teaches a blister package device comprising a foil type package for storing medicament (col. 1, lines 66-67) composed of plastic polymers (col. 2, lines 54-65).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to apply the method of Caburet to the device of Leblong because it reduces the coefficient of friction in the device which will prevent the medicament from adhering to the device.

5. Claims 34-40 and 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,131,566 to Ashurst et al. in view of US 5,576,068 to Caburet et al. and in further view of US 5,349,944 to Chippendale et al.

Ashurst teaches a method comprising the step of using plasma polymerization to create a layer of one or more plasma polymerized monomers bonded to at least a portion of one or more internal surfaces of an inhaler apparatus (col. 2, lines 15-30).

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Ashurst is silent with regards to the specific components of the inhaler or the monomer being siloxanes.

Caburet teaches a method of using cold plasma polymerization on a surface of a medical storage device in order to reduce the coefficient of friction, which prevents the medication from adhering to the device; and wherein the cold plasma polymerized polymer is siloxane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use cold plasma polymerized siloxane in the method of Ashurst because it is known in the art to use different types of polymers for cold plasma polymerization. Though the Ashurst and Caburet references disclose applying polymerized polymers to different devices, both references uses polymerized polymers to prevent medicament from adhering to the devices.

The combination of Ashurst/Caburet is still silent with regards to the specific components of the inhaler.

Chippendale teaches a metered dose inhaler having a metering valve comprising a valve stem **5** co-axially slidable within a valve member, the valve member and valve stem defining an annular metering chamber, outer and inner rubber annular seals **3,4** operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween. Chippendale also teaches the metered dose inhaler having a housing adapted to receive a container having said metering valve, a mouthpiece, and a duct.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the metered dose inhaler of Ashurst include the specific components of Chippendale because it is well known in the art to have a metering valve in a metered dose inhaler. Furthermore, it would have been obvious to have the different recited components include a layer of cold plasma polymerized polymer because Ashurst teaches that any part of the metered dose inhaler could have a layer of polymerized polymers.

Response to Arguments

6. Applicant's arguments with respect to claims 32-40 and 42-46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GLENN K. DAWSON
PRIMARY EXAMINER